DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 27, 2014

Defibtech, LLC
Mr. Ed Horton
Vice President Quality Assurance and Regulatory Affairs
741 Boston Post Rd., Suite 201
Guilford, CT 06437

Re: K141809
Trade/Device Name: RMU-1000 Automated Chest Compressor (ACC) System
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class III
Product Code: DRM
Dated: October 3, 2014
Received: October 6, 2014

Dear Mr. Horton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

Ver/ 3 - 4/24/96

510(k) Number (if known): K141809

**Date Prepared:** October 2014

**Applicant**

Defibtech, LLC

**Device Name**

RMU-1000 Automated Chest Compression (ACC) System

**Indications For Use**

The RMU-1000 ACC is intended for use as an adjunct to manual cardiopulmonary resuscitation (CPR) when effective manual CPR is not possible (e.g., during patient transport, or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient personnel are available to provide effective CPR).

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

| | | |
|---|---|---|
| Prescription Use_____**X**___<br>(Per 21 CFR 801.109) | AND/OR | Over-the-counter Use_____<br>(Per 21 CFR 807 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

# 510(k) Summary

## 1. Date Summary Prepared

October 17, 2014

## 2. 510(k) Owner Information

Defibtech, LLC
741 Boston Post Road
Guilford, CT 06437

## 3. Primary Contact Information

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## 4. Trade (Proprietary) Name

RMU-1000 Automated Chest Compression (ACC) System

## 5. Common Name

Mechanical chest compressor

## 6. Regulation/Classification Name and Code

External Cardiac Compressor (product code DRM)

## 7. Regulation/Classification Code

21 CFR 870.5200

## 8. Predicate Device Information

The predicate device is the LUCAS Chest Compression System, which has been previously cleared in various 510(k) submissions. The RMU-1000 ACC is substantially equivalent in performance and safety to the LUCAS and accessories cleared under the following:

| **Proprietary Name** | **Manufacturer** | **Submission Number** |
|---|---|---|
| LUCAS2 Chest Compression System | Jolife AB | #K090422 |

## 9. Device Description

The RMU-1000 Automated Chest Compression (ACC) System is an automated, portable, battery-powered device that provides chest compressions on adult patients who have cardiac arrest. The RMU-1000 ACC, when applied to a patient who is unconscious and not breathing, is designed to:

- Provide consistent depth and rate chest compressions.
- Allow for automated chest compressions in both the in-hospital and out of hospital settings, including during patient transport.
- Be applied to the patient with minimal interruption of CPR.

The major elements of the RMU-1000 ACC are the Backboard, Frame and Compression Module. The Backboard is placed under the patient to provide a base for the RMU-1000 ACC system. The Frame is placed over the patient and snaps into the Backboard with two self-locking latches, one on each side of the Frame. The Compression Module mounts into the Frame and contains the user interface, the replaceable/rechargeable lithium ion battery and the piston drive (and motor) used to generate the chest compressions. A replaceable, single-use Patient Interface Pad at the distal end of the Piston contacts the patient's chest and serves to soften the edges of the Piston during compressions.

Compression rate and depth, performed according to current American Heart Association (AHA) and other internationally-recognized resuscitation guidelines, are initiated using a simple three-step operational sequence once the RMU-1000 ACC has been applied to a patient:

- the Compression Module is turned on by pressing the power button;
- the Piston height adjusted for the patient's chest size by pressing the appropriate height adjust button; and
- the appropriate compressions button pushed (either continuous compressions or an automatic pause for breaths).

Additional user interface features include a compression pause function button, service warning indicator, warning mute button, and battery capacity gauge.

The RMU-1000 ACC can be operated using a replaceable, rechargeable lithium-ion battery pack or with an external power supply. A fully-charged, new battery can provide continuous operation for over an hour and can be recharged while in the Compression Module.

A USB port on the Compression Module allows maintenance functions to be performed (outside of emergency use) through a connection to a personal computer.

The RMU-1000 ACC fits in a carry case that holds all the various System elements and accessories, spares (optional) and labeling.

**10. Indications for Use/Intended Use**

Indications for Use

The RMU-1000 ACC is intended for use as an adjunct to manual cardiopulmonary resuscitation (CPR) when effective manual CPR is not possible (e.g., during patient transport, or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient personnel are available to provide effective CPR).

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

## 11. Comparison of Technology Characteristics

The operating principles and basic design of the RMU-1000 ACC are the same as those in the LUCAS 2 predicate device. These similarities also include device features, such as the compression mechanism, power sources, deployment operations, and user interface controls. The patient characteristics that the devices treat are similar (adult patients) and compression parameters given to the patients are the same for both devices. Both the Defibtech RMU-1000 and the predicate use a DC motor that powered by a rechargeable battery or an external DC source that in turn drives screw drive piston. And both devices are designed to meet the same resuscitation guideline recommendations, marketed for the same clinical applications and used by the same types of users in similar use environments.

In comparison, the technology differences between the RMU-1000 ACC and the predicate device includes an electronically driven piston height adjustment, the ability to download internal memory stored in the Compression Module when the RMU-1000 ACC is not being used in an emergency, the use of a lithium-ion battery chemistry and a mechanical patient interface pad design. The differences between the devices are not significantly clinically different and are related to design enhancements for users and implementation decisions. The indications for use of the RMU-1000 ACC reflect the September 11, 2013 FDA Circulatory Systems Device Panel of the Medical Devices Advisory Committee meeting and FDA's proposed reclassification of this product code into class II (reference 78 FR 49272, August 13, 2013, Docket No. FDA-2013-N-0001), whereas the predicate's indications for use statement does not consider the current regulatory developments for this device classification type.

## 12. Performance testing

The RMU-1000 ACC uses the same underlying technologies to provide functionally equivalent performance characteristics as the predicate device. Testing, including hardware verification, software validation, design validation, and compression waveform comparison, demonstrates that the DDU-1000 meets functional and/or performance specifications. Safety testing, including IEC 60601-1 for the "Medical electric equipment : General requirements for basic safety and essential performance", IEC 60601-1-2 for "General Requirements for Safety – Collateral Standard: Electromagnetic compatibility – Requirements and Tests" and IEC 62133 "Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications," assures compliance with applicable industry safety standards.

**13. Conclusion Summary of Safety and Effectiveness**

Testing and performance evaluations demonstrate that the RMU-1000 ACC is substantially equivalent to the predicate device. The introduction of the RMU-1000 ACC does not present new issues of safety or effectiveness.